US experts meet ahead of expected Moderna vaccine approval

17 December 2020

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US experts were holding a meeting Thursday where they were expected to recommend approval of Moderna's COVID-19 vaccine, paving the way for six million doses to start shipping this weekend.

The meeting comes as the number of deaths from the coronavirus quickly approaches 310,000 in the worst-hit country in the world, which this week began vaccinating health care workers and long-term care residents with the Pfizer-BioNTech vaccine.

Both of these frontrunners are based on cutting-edge mRNA (messenger ribonucleic acid) technology, which had never been approved prior to the pandemic, and both are two-dose regimens.

Though the level of protection against COVID-19 for both is around 95 percent—far greater than experts had thought was possible—there have now been a handful of people around the world who developed significant allergic reactions after receiving the Pfizer vaccine.

Thursday's meeting was being live-streamed, and will end with a vote by the two dozen independent scientists and industry representatives.

Should the panelists vote in favor, as is expected, it is believed the Food and Drug Administration would soon thereafter issue its green light.

That would make the US, which has recorded more than 17 million cases of the virus, the first country to approve the Moderna vaccine.

The small Massachusetts-based biotech firm teamed up with scientists from the US National Institutes of Health on the product and has received more than $2.5 billion from the US government for its efforts.

Protection against infection

A clinical trial of 30,400 people found it was 94.1 percent effective in preventing COVID-19 compared to a placebo, performing slightly better in younger adults compared to the elderly.

Jacqueline Miller, Moderna's vice president of infectious diseases development, added Thursday that there was a strong suggestion the vaccine also protected most people against infection, which is important from a public health perspective as it would prevent onward transmission.

An FDA review of all available data found there were "no specific safety concerns identified that would preclude issuance of an EUA (emergency use authorization)."

But on Thursday, FDA official Doran Fink said that should an EUA be granted, the agency would issue a beefed-up warning label regarding potential allergic reactions.

This comes after two health care workers in Alaska had such reactions to the Pfizer vaccine, and one of them was hospitalized. Two health workers in the

UK also had allergic reactions.

Tal Zaks, Moderna's chief medical officer, stressed that the two vaccines were not identical and side effects may differ.

- Placebo dilemma-

Moderna was criticized by Stanford expert Steven Goodman because of its plans to offer the vaccine to participants in its trial who received the placebo, even before it would normally be available to their demographic group.

This would deprive the trial of a control group and reduce the quality of data that could be gleaned from it, and set a bad precedent for future trials, he said.

But Zaks defended the proposal.

"None of our trial participants would be 'jumping the line' ahead of others, because we have clinical trial supplies that in fact would expire and go to waste," he said, adding many participants were at high-risk, and one person on the placebo group had died from severe COVID-19.

The most common side effects associated with the drug, called mRNA-1273, were injection site pain in roughly 90 percent of cases; fatigue in 70 percent, headache in 60 percent, muscle pain in 60 percent, joint pain in 45 percent and chills in 45 percent.

Few of these effects were classed as "severe."

Allergic reactions occurred in 1.5 of the vaccinated population compared to 1.1 percent of the non-vaccinated, but none were classed as severe.

To date, there have been three reports of Bell's palsy—a facial paralysis condition, most often temporary—in the vaccine group and one in the placebo group.

The Pfizer trial saw four people get Bell's palsy in the vaccine group, and none in the placebo group.

The FDA said there was insufficient information to determine that either vaccine was the cause but will continue monitoring.

Each has a different cold-storage requirements: -70 degrees Celsius (-94 degrees Fahrenheit) for Pfizer; -20 degrees Celsius (-4 Fahrenheit) for Moderna. Moderna has applied for approval for people 18 and older, while Pfizer's approval is for people 16 and older.